



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-23-22ER]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled "Formative Respirator and Protective Clothing Laboratory Testing" to the Office of Management and Budget (OMB) for review and approval. CDC previously published a "Proposed Data Collection Submitted for Public Comment and Recommendations" notice on May 6, 2022, to obtain comments from the public and affected agencies. One public comment was received. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

- (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

- (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- (c) Enhance the quality, utility, and clarity of the information to be collected;
- (d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and
- (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to [www.reginfo.gov/public/do/PRAMain](http://www.reginfo.gov/public/do/PRAMain). Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

## Proposed Project

### Formative Respirator and Protective Clothing Laboratory Testing

- NEW - National Institute for Occupational Safety and Health

(NIOSH), Centers for Disease Control and Prevention (CDC).

### Background and Brief Description

The Centers for Disease Control and Prevention (CDC), National Institute for Occupational Safety and Health (NIOSH), is requesting approval of a New Generic Information Collection Request (ICR) for a period of three years under the project titled "Formative Respirator and Protective Clothing Laboratory Testing." The National Personal Protective Technology Laboratory (NPPTL) is a division of the NIOSH which operates within the CDC. NIOSH is the federal institute specifically dedicated to generating new knowledge in the field of occupational safety and health and responsible for transferring that knowledge into practice for the betterment of workers.

NPPTL was established in 2001, at the request of Congress, with the mission of preventing disease, injury, and death for the millions of working men and women relying on personal protective technology (PPT). PPT plays an important role in keeping many workers within various industries safe while performing their professional duties. To achieve the Laboratory's mission, NPPTL conducts scientific research, develops guidance and authoritative recommendations,

disseminates information, and responds to requests for workplace health hazard evaluations. The development of NPPTL filled a need for improved personal protective equipment (PPE) and focused research into PPT.

Respiratory protection, a specific type of PPE commonly tested by NPPTL, is the cornerstone of NPPTL's efforts. One of the primary responsibilities of the Laboratory is to test and approve respirators used in U.S. occupational settings. This function ensures a standard level of quality and filtration efficiency for all respirators used within a U.S. workplace setting. The NPPTL Respirator Approval Program exists to increase the level of worker protection from airborne particulates, chemicals, and vapors. In addition to respirators, NPPTL conducts research on other types of PPE, including chemical-resistant clothing, hearing protection, gloves, eye and face protective devices, hard hats, sensors to detect hazardous substances, and communication devices used for safety deployment of emergency workers. NPPTL PPE research examines exposure to inhalation hazards, dermal hazards, and any other hazardous environmental threats within an occupational setting.

PPE performance requirements and test methods are specified within: (1) federal regulations by NIOSH, Food and Drug Administration (FDA), and the Mine Safety and Health Administration (MSHA); and (2) voluntary consensus standards published by organizations such as the American National Standards Institute (ANSI), American Society for Testing and

Materials (ASTM) International, and International Organization for Standardization (ISO). Thus, the information collected from human subjects in a laboratory setting are generally consistent across NPPTL studies with only the boundary conditions changing (e.g., environmental conditions such as heat or humidity, human subject activity such as simulated surgery or climbing a ladder, distance between two subjects communicating by spoken word, various PPE use durations, or the use of novel PPE designs). Considering these consistent data collection methods employed with only changes in boundary conditions specified to a specific industry or standard, NPPTL requests a Generic ICR package for laboratory-collected information for testing respirators and protective clothing.

The resulting data will benefit the federal government in that the performance standards and test methods supported will directly aid in ensuring the adequate protection via PPE of workers across a variety of industry sectors. Furthermore, the continued research in these methods will ensure the performance standards and test methods are up to date with an ever-evolving workplace safety climate, as well as technological advancements in PPE. Through this data collection, the federal government will ultimately be able to efficiently react to the PPE protection needs of workers across the country thereby fulfilling CDC/NIOSH's mission.

The methods used to collect the information from human participants will include health screenings, demographic

information collection instruments, psychometrically supported surveys of user experience and perception of PPE, direct physiological measurements of response to PPE, biological measures of physiological responses, anthropometric measures of body size and shape, measures of PPE fit, and measures of the body's movement through space (biomechanics). The respondent universe for the proposed data collection will be recruited from the general population but their demographic characteristics are expected to be reflective of the full spectrum of the U.S. workforce and from industries that rely heavily on PPE to protect workers (e.g., healthcare and social assistance, public safety and emergency response, and agriculture). Because the U.S. worker population in some cases includes children down to the age of eight years in certain industries such as agriculture, it is expected that studies included in this data collection may also include children. Because respondents will be recruited via a variety of different avenues (email, flyers, advertisements, etc.), it is expected that the respondent pool will vary in gender, age, race/ethnicity, persons residing in rural and/or urban locations, and/or in specific regions or health jurisdictions. Additionally, pregnant women may also be a focus of these data collection efforts as pregnant women are regular users of PPE which must be considered due to specific needs related to changes in body shape and size.

CDC estimates that up to 1,750 individuals could be burdened per year with an estimated annualized burden of 15,591

hours. There is no cost to respondents other than their time to participate.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)
Members of the general public	Informed Consent	970	1	30/60
	Health Screening Questionnaire: Standardized form w/ decision logic allowing some questions to be omitted	970	6	1
	Demographics Questionnaire: Standardized form w/ decision logic allowing some questions to be omitted, W-9 Tax Form, etc.	970	1	30/60
	Job-related Data: Occupational tasks, postures used, duration of exposure, etc.	970	1	15/60
	Physiological Measurements: Chest-worn heart rate monitor strap, COSMED Kb5, SQ2020-1F8 temperature logger, TOSCA 500 pulse oximeter, koken breathing waveform recording mask, etc.	200	6	1.5
	Biological Measurements: Cortisol (stress) levels, pregnancy tests, hydration status, lipids, inflammatory markers, heat shock proteins, etc.	100	6	15/60
	Anthropometric Measurements: Calipers/digital measuring of facial and body dimensions	750	1	15/60

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)
	Respirator Fit Measurements: Filter cassettes with air pumps, fit-testing equipment, QLFT/sodium saccharin solution etc.	225	100	15/60
	Self-Perception Data: Level of exertion, perceived comfort level, heat sensation, fatigue, etc.	500	6	15/60
	Biomechanics Measurements: Force plate, stopwatch, accelerometers, etc.	30	3	30/60

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[FR Doc. 2022-22928 Filed: 10/20/2022 8:45 am; Publication Date: 10/21/2022]